

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION**

**HALL'S IV AND INSTITUTIONAL
PHARMACY, INC. D/B/A
XPRESS COMPOUNDING**

Plaintiff,

v.

PRIME THERAPEUTICS, LLC

Defendant.

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CIVIL ACTION NO. 4:16-CV-00019-O

**PLAINTIFF'S MOTION FOR
PRELIMINARY INJUNCTION AND BRIEF IN SUPPORT**

Respectfully submitted,

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TABLE OF CONTENTS

| | | |
|------|---|----|
| I. | INTRODUCTION & SUMMARY..... | 1 |
| II. | FACTUAL BACKGROUND..... | 4 |
| III. | ARGUMENT & AUTHORITIES | 9 |
| A. | Injunctive Relief Is Warranted Upon A Showing Of Four Elements | 9 |
| B. | Xpress Compounding Has Established All Four Elements Justifying A Preliminary Injunction | 10 |
| 1. | There Is A Substantial Likelihood That Xpress Compounding Will Prevail On The Merits Of Its Declaratory Relief Claim | 10 |
| a. | Prime Is Not Entitled To Terminate Xpress Compounding Without Cause Under Article 21.52B Of The Texas Insurance Code..... | 10 |
| b. | There Is No Valid Basis For Termination From Prime’s Network For Purposes Of Article 21.52B Of The Texas Insurance Code..... | 12 |
| c. | Prime Is Required To Provide Xpress Compounding A Written Explanation For The Reasons For Its Termination Under Section 843.306(a) Of The Texas Insurance Code..... | 14 |
| d. | Xpress Compounding Is Entitled To Have Prime’s Termination Decision Reviewed By An Advisory Review Panel Under Section 843.306(b) Of The Texas Insurance Code..... | 15 |
| 2. | Unless Enjoined, Prime’s Wrongful Termination Will Result In Immediate, Irreparable Injury To Xpress Compounding And Its Patients | 16 |
| a. | Termination Will Cause A Loss Of Business, Reputation And Customer Goodwill For Existing And Future Patients | 16 |
| b. | Termination Will Result In Risk To Patient Health..... | 21 |

| | | |
|-----|--|-----|
| 3. | Prime Will Sustain No Harm From The Preliminary Injunction Sought Herein, Much Less Any Harm That Outweighs The Immediate, Irreparable Harm To Xpress Compounding Absent An Injunction | 22 |
| 4. | Enjoining Prime From Terminating Xpress Compounding Will Not Undermine The Public Interest | 23 |
| IV. | PRAYER..... | 24 |
| | CERTIFICATE OF CONFERENCE..... | 255 |
| | CERTIFICATE OF SERVICE | 26 |

TABLE OF AUTHORITIES

| | Page(s) |
|---|-----------|
| Cases | |
| <i>Austin Bd. of Realtors v. E-Realty, Inc.</i> , 2000 WL 34239114 (W.D. Tex. Mar. 30, 2000) | 16, 22 |
| <i>Byrum v. Landreth</i> , 566 F.3d 442 (5th Cir. 2009) | 9 |
| <i>In re Compounding Pharmacy, Inc. Prod. Liab. Litig.</i> , 496 B.R. 256 (D. Mass. 2013) | 17 |
| <i>Dallas Cnty. v. Bureau of Justice Assistance</i> , 988 F. Supp. 1030 (W.D. Tex. 1996)..... | 23 |
| <i>Daniels Health Sciences v. Vascular Health</i> , 710 F.3d 579 (5th Cir. 2013) | 23 |
| <i>Dr. Mark Lynn & Assocs. PLLC v. Vision Serv. Plan Ins. Co.</i> , 2005 WL 2739160 (W.D. Ky. Oct. 21, 2005) | 20 |
| <i>Humana, Inc. v. Jacobson</i> , 804 F.2d 1390 (5th Cir. 1986) | 9, 16, 20 |
| <i>Incubus Invs. L.L.C. v. City of Garland</i> , 2003 2003 WL 23095680 (N.D. Tex. Dec. 17, 2003) | 10 |
| <i>J.C. Penney Co. v. Giant Eagle, Inc.</i> , 813 F. Supp. 360 (W.D. Pa. 1992)..... | 20 |
| <i>Kentucky Assoc. of Health Plans, Inc. v. Miller</i> , 538 U.S. 329 (2003)..... | 12 |
| <i>Lakedreams v. Taylor</i> , 932 F.2d 1103 (5th Cir. 1991) | 10 |
| <i>Paduano v. Express Scripts Inc.</i> , Case No. 2:14-cv-05376-ADS-ARL (E.D.N.Y. Oct. 3, 2014) | 20 |
| <i>Pharmacy Ass’n v. Prudential Ins. Co. of Am.</i> , 907 F. Supp. 1019 (W.D. Tex. 1995), <i>aff’d in part and rev’d in part</i> , 105 F.3d 1035 (5th Cir. 1997)..... | 11, 12 |
| <i>PharMerica Corp. v. Mary Jo McElyea & Absolute Pharm., Inc.</i> , 2014 WL 1876271 (N.D. Ohio May 9, 2014)..... | 20 |

| | |
|--|--------|
| <i>Planned Parenthood Ass’n of Hidalgo Cnty. v. Suehs</i> , 828 F. Supp. 2d 872 (W.D. Tex. 2012)..... | 22 |
| <i>Planned Parenthood of Cent. Tex. v. Sanchez</i> , 280 F. Supp. 2d 590 (W.D. Tex. 2003)..... | 16, 22 |
| <i>Sebastian v. Tx. Dept. of Corrections</i> , 541 F. Supp. 970 (S.D. Tex. 1982) | 10 |
| <i>Teladoc, Inc. v. Tex. Med. Bd.</i> , 2015 WL 4103658 (W.D. Tex. May 29, 2015) | 24 |
| <i>Tex. Democratic Party v. Benkiser</i> , 459 F.3d 582 (5th Cir. 2006) | 23 |
| <i>Tex. Health Care Ass’n v. Bowen</i> , 710 F. Supp. 1109 (W.D. Tex. 1989)..... | 22 |
| <i>Thomas v. Johnston</i> , 557 F. Supp. 879 (W.D. Tex. 1983)..... | 22 |
| <i>Union Planters Bank, N.A. v. Gavel</i> , 2003 WL 1193671 (E.D. La. Mar. 12, 2003) | 23 |
| <i>United Healthcare Ins. Co. v. AdvancePCS</i> , 2002 WL 432068 (D. Minn. Mar. 18, 2002) | 20 |
| <i>WB Music Corp. v. Big Daddy’s Entm’t, Inc.</i> , 2005 WL 2662553 (W.D. Tex. Oct. 18, 2005) | 22 |

Statutes

| | |
|---|---------------|
| TEX. INS. CODE Article 21.52B | <i>passim</i> |
| TEX. INS. CODE Section 843.306(a) | 14, 15 |
| TEX. INS. CODE Section 843.306(b) | 7, 15, 16 |

Other Authorities

| | |
|--|----|
| David Ott, <i>Balancing the DOD's Compounding Equation</i> , THE HILL (Apr. 1, 2015), http://thehill.com/blogs/congress-blog/healthcare/237540-balancing-the-dods-compounding-equation | 17 |
| Kurt Eichenwald, <i>The Killer Pharmacy: Inside a Medical Mass Murder Case</i> , NEWSWEEK (Apr. 16, 2015), http://www.newsweek.com/2015/04/24/inside-one-most-murderous-corporate-crimes-us-history-322665.html | 17 |
| Maggie Fox, <i>Don't Use Dallas Compounding Pharmacy Products, FDA Warns</i> , NBC NEWS (Aug. 16, 2013), http://www.nbcnews.com/health/dont-use-dallas-compounding-pharmacy-products-fda-warns-6C10937607 | 17 |
| TEX. ATT'Y GEN. OP. NO. KP-0036 (Aug. 14, 2015) | 15 |

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provider network. Prime has not asserted and cannot show that Xpress Compounding has materially breached this agreement.

Prime has alleged that the termination, to become effective on January 29, 2016, is premised on so-called “poor audit performance.” Prime is wrong. Nothing in Xpress Compounding’s audit history justifies termination. The sole site audit performed by Prime prior to announcing the termination resulted in recoupment of less than twelve percent (12%) of claim revenue represented by the prescriptions at issue in the audit period. This is not a material breach, nor evidence of an unwillingness by Xpress Compounding to comply with generally applicable terms and conditions. Historically, pharmacies have performed comparably or even much worse without being subject to termination. Likewise, nothing in the desktop audits and information requests made by Prime within the last eighteen months shows any lack of compliance or warrants termination. Under the clear terms of article 21.52B, Prime is not entitled to terminate Xpress Compounding “without cause,” and nothing in Xpress Compounding’s audit history can justify termination “for cause.”

The Texas Insurance Code also requires PBMs like Prime to explain the basis for termination of a pharmacy provider like Xpress Compounding. PBMs are also obligated to provide review of termination decisions by an “advisory review panel” prior to the effective date of termination. Despite direct requests from Xpress Compounding, Prime has not complied with either statutory requirement. Accordingly, Xpress Compounding is entitled to the declaratory relief sought in this action and likely to prevail on the merits of these claims.

Absent a preliminary injunction preserving Xpress Compounding’s participant status in Prime’s provider network, both Xpress Compounding and its patients will suffer imminent and irreparable harm. Prime’s termination is stated to take effect on January 29, 2016. If terminated,

Xpress Compounding will lose the opportunity to serve any existing patients insured under Prime-affiliated plans. Xpress Compounding will not just lose the revenue anticipated from these customers. As patients are forced to undertake the unpleasant process of finding a new pharmacy and transitioning prescriptions away from their preferred place of business—all because of a dubious network termination—any goodwill or positive reputation that Xpress Compounding has enjoyed with these patients until now will be irretrievably lost. Xpress Compounding's reputation as a reliable provider of safe and effective compounded medications would be sullied among patients and physicians who rely on Xpress Compounding's participation in Prime's network as an indicator of quality.

Moreover, Xpress Compounding will not only lose existing patients, it will lose relationships with members of plans unaffiliated with Prime, as referring physicians (unable to differentiate easily between Prime and non-Prime patients) shift their entire business to an alternative pharmacy. As existing patients and physician referrals are lost, an undefined number of future patients will go with them.

In the event of a termination, individual health will also be threatened. Patients depend upon quality compounded pharmaceuticals to fight infection, manage pain and avoid adverse side-effects sometimes associated with conventional medications. If Prime's patients are unable to maintain a consistent supply of medications—particularly during the delays that often accompany transitions from one pharmacy to another—patients may sustain infection, experience greater pain, and suffer from side-effects and longer recovery periods, among other complications.

The imminent and inevitable damage either to Xpress Compounding's reputation and customer goodwill, on the one hand, or to the health of Prime's patients, on the other hand,

represents immediate and irreparable injury justifying injunctive relief. This harm is not and cannot be outweighed by any injury claimed by Prime. Nor will an injunction disserve the public interest. Neither Prime nor the public can be harmed by Prime's compliance with the Texas Insurance Code.

Because (1) Xpress Compounding's declaratory judgment claims have merit; (2) immediate and irreparable harm will ensue in the absence of an injunction; (3) the harm to Prime from an injunction in no way exceeds the anticipated harm to Xpress Compounding or its patients; and (4) an injunction will not disserve the public interest, Xpress Compounding's Motion should be granted in its entirety. Due to the urgency created by the anticipated expiry of the existing state district court's temporary restraining order, Xpress Compounding respectfully requests the Court grant a hearing on this Motion on or before January 20, 2016.

II. FACTUAL BACKGROUND

1. Xpress Compounding is a licensed sterile prescription and compounding pharmacy, founded in 2014. Ex. 1 (App. 001) (Hall Aff., ¶ 2).

2. Xpress Compounding provides both conventional and compounded medications to patients throughout Texas. *Id.* at ¶ 2.

3. Unlike traditional prescription medications, which are mass produced and sold in pre-formulated quantities, compounded pharmaceuticals are customized to meet a specific patient's individual needs when traditional medications are not commercially available or when customized medications are required. *Id.* at ¶ 7 (App. 003). Xpress Compounding's sterile compounded medications include antibiotics, pain management tools, and hormone treatments, among others. *Id.* Xpress Compounding also prepares customized topical pain, scar and wound care management formulations. *Id.*

4. Unlike some compounding pharmacies, which struggle to provide quality and consistency in their products, Xpress Compounding has a record of providing quality, safe compounded medications to patients and enjoys a positive reputation in the medical community. *Id.* at ¶ 8-9 (App. 003-004); Ex. 2 (App. 008-009) (Kretzschmar Aff., ¶ 5-6).

5. Xpress Compounding has devoted significant resources into creating a state-of-the-art compounding facility, with the equipment and trained pharmacy staff needed to formulate premium compounded pharmaceuticals. Ex. 1 (App. 003) (Hall Aff., ¶ 6). Xpress Compounding's lab has been certified as compliant with USP Chapter 797 sterility standards and has also been accredited by the Pharmacy Compounding Accreditation Board, an organization formed in 2006 to certify the quality of compounding pharmacies in the United States. *Id.*

6. Prime is a pharmacy benefit manager, which operates as an intermediary between pharmacies and the health insurance plans insuring Xpress Compounding's customers. Ex. 1 (App. 004) (Hall Aff., ¶ 11). Prime is primarily responsible for paying pharmacies for prescription drugs provided to the member beneficiaries of the health plans and health insurance policies it administers. *Id.* at ¶ 12 (App. 004-005).

7. In March 2014, Xpress Compounding entered into a PBA Health Services Agreement with Pharmacy Buying Association, Inc. ("TriNet" or "PBA Health"), whereby Xpress Compounding and TriNet agreed that TriNet would act as agent for Xpress Compounding in entering into network agreements with pharmacy benefit managers ("PBMs"), like Prime. Ex. 3 (App. 013) (Paprskar Aff., ¶ 8); Ex. 3-B (App. 035-044) (PBA Agreement). Xpress Compounding is a member of Prime's pharmacy network pursuant to a Pharmacy Participation Agreement between Prime and PBA Heath. Ex. 3 (App. 013) (Paprskar Aff., ¶ 7); Ex. 3-A (App. 018-034) (PPA Agreement).

8. Under the PBA Agreement, Xpress Compounding explicitly agreed to “comply with all Terms and Conditions set forth in all Pharmacy Benefit Manager (PBM) Network Agreements contracted by TriNet on Client’s behalf . . .”, including the PPA Agreement. Ex. 3-B (App. 042) (TriNet Third Party Network Addendum, at ¶ 1.1).

9. On October 22, 2015, Prime sent a letter notifying Xpress Compounding that Prime was terminating Xpress Compounding from Prime’s pharmacy network, effective January 29, 2016. Ex. 3 (App. 015-016) (Paprskar Aff., ¶ 17); Ex. 3-K (App. 251) (Oct. 22, 2015 letter).

10. In its October 22, 2015 letter, Prime stated that Xpress Compounding had “recently exhibited poor audit performance evidencing failure to comply with Prime’ [sic] terms and conditions as outlined in the Pharmacy Participation Agreement and Provider Manual.” Ex. 3-K (App. 251). Prime did not identify any specific terms or conditions or refer to any specific audit findings. *Id.*

11. Over the past twelve months, Prime has conducted one site audit on January 28, 2015; issued a series of twenty-one desktop audits; and made one wholesaler inventory request. Ex. 3 (App. 014-015) (Paprskar Aff., ¶¶ 9, 14, 16).

12. After corrections and an appeal, the January 28, 2015 site audit, which reviewed \$41,810.26 in claims submitted between September 2014 and November 30, 2014, resulted in a recoupment of \$4,978.34 or 11.67% of all claims at issue by revenue. Ex. 3 (App. 014) (Paprskar Aff., ¶¶ 9-13); Ex. 3-G (App. 166-198) (Prime’s Sept. 3, 2015 appeal response).

13. Prime’s twenty-one desktop audits did not result in any adverse finding or disciplinary action against Xpress Compounding. Ex. 3 (App. 014-015) (Paprskar Aff., ¶ 14); Ex. 3-H (App. 199-219) (desktop audit summary). Nor did Prime’s wholesaler invoice request.

Ex. 3 (App. 015) (Paprskar Aff., ¶ 16); Ex.3-J (App. 250) (Prime's wholesaler inventory request).

14. None of the audits performed prior to Prime's October 22, 2015 termination notice indicates an unwillingness to comply with the terms of any contract or other requirement imposed by Prime upon other pharmacies within its network. Ex. 3 (App. 014-015) (Paprskar Aff., ¶¶ 10-16); Ex. 3-G (App. 166-198) (Prime's appeal response); Ex. 3-H (App. 199-219) (audit summary); Ex. 4 (App. 256-257) (Alexander Aff., ¶ 6).

15. On November 9, 2015, Xpress Compounding sent a letter to Prime (1) requesting an explanation of the basis of Prime's termination notice; and (2) demanding review by an advisory review panel under Section 843.306(b) of the Texas Insurance Code. Ex. 3-L (App. 252-53).

16. Xpress Compounding asserted that termination from Prime's pharmacy provider networks without cause violates article 21.52B of the Texas Insurance Code, which prohibits pharmacy network operators, like Prime, from limiting provider participation in the network by any pharmacy or pharmacist, who agrees to comply with the standard terms and requirements to which other participating pharmacies and pharmacists are subject. *Id.*

17. On December 22, 2015, Prime notified Xpress Compounding that it had considered Xpress Compounding's termination appeal and that it had decided to uphold the termination. Ex. 3-M (App. 254). Prime did not identify any specific terms or conditions in its Pharmacy Participation Agreement or Provider Manual with which Xpress Compounding has failed to comply. *Id.*; Ex. 3 (App. 015-016) (Paprskar Aff., ¶¶ 15, 17, 19).

18. Prime did not respond in any manner to Xpress Compounding's assertion that termination without cause violates article 21.52B of the Texas Insurance Code. Ex. 3 (App. 016)

(Paprskar Aff., ¶ 19); Ex. 3-M (App. 254) (Dec. 22, 2015 letter). Nor did Prime respond to Xpress Compounding's demand for review by an advisory review panel under Section 843.306(b) of the Texas Insurance Code. Ex. 3 (App. 016) (Paprskar Aff., ¶ 19); Ex. 3-M (App. 254) (Dec. 22, 2015 letter).

19. On January 5, 2016, Xpress Compounding filed its Verified Original Petition, Application for Temporary Restraining Order, and Request for Injunctive Relief in Tarrant County District Court. Doc. No. 1-3. The Tarrant County District Court issued a Temporary Restraining Order preventing Prime from terminating Xpress Compounding from its network through January 20, 2016. Doc. No. 1-3 at 15-16. Prime thereafter removed the case to this Court. *See* Doc. No. 1. Xpress Compounding now seeks a preliminary injunction pending the resolution of its claims in this litigation.

20. If Prime's termination is not enjoined, Xpress Compounding's reputation and customer goodwill will be irretrievably lost. Xpress Compounding will lose all those existing customers insured under Prime-affiliated health plans and policies, along with any accumulated customer goodwill as those patients are notified of the termination and forced to undergo the confusing, cumbersome and time consuming process of transferring to a new pharmacy. Ex. 1 (App. 005-006) (Hall Aff., ¶¶ 14, 17); Ex. 2 (App. 009) (Kretzschmar Aff., ¶ 7); Ex. 4 (App. 257-258) (Alexander Aff., ¶¶ 10-13); Ex. 5 (App. 261-262) (Howell Aff., ¶¶ 5-10).

21. A termination of Xpress Compounding from Prime's pharmacy provider network will not only destroy customer relationships with current Prime patients, but will damage Xpress Compounding's reputation and make it less likely for some physicians to refer patients—whether insured through an Prime plan or not—to Xpress Compounding. Ex. 2 (App. 009-010) (Kretzschmar Aff., ¶¶ 7, 11); *see also* Ex. 1 (App. 005-006) (Hall Aff., ¶¶ 14, 15). This would

affect not only Xpress Compounding's compounded-medication business but also its conventional prescription business. *Id.*

22. Xpress Compounding will also lose an untold number of future patients, including potential referrals from Prime, existing patients and physicians. Ex. 1 (App. 006) (Hall Aff., ¶ 16); Ex. 2 (App. 009-010) (Kretzschmar Aff., ¶¶ 7, 11); Ex. 5 (App. 262) (Howell Aff., ¶ 10).

23. Termination from Prime's network will also threaten Xpress Compounding's relationship with other PBMs, who inquire about network terminations generally in periodic credentialing applications to remain a part of other PBM networks. Ex. 3 (App. 016-017) (Paprskar Aff., ¶¶ 21-22).

24. Moreover, if Prime is not enjoined from terminating Xpress Compounding from its pharmacy provider network, patient health will be placed at risk as patients may be unable to obtain needed drugs during the days required to transfer prescriptions from Xpress Compounding to alternative pharmacies within Prime's network. Ex. 2 (App. 009-010) (Kretzschmar Aff., ¶ 9); Ex. 4 (App. 258) (Alexander Aff., ¶ 14); Ex. 5 (App. 261) (Howell Aff., ¶¶ 7-8).

III. ARGUMENT & AUTHORITIES

A. Injunctive Relief Is Warranted Upon A Showing Of Four Elements.

In order to prevail on a motion for a preliminary injunction, the movant must establish that (1) there is a substantial likelihood of success on the merits; (2) there is a substantial threat of irreparable harm if the injunction is denied; (3) the threatened injury to the movant outweighs any harm to the non-movant that may result from the injunction; and (4) granting the injunction will not disserve the public interest. *Byrum v. Landreth*, 566 F.3d 442, 445 (5th Cir. 2009). The issuance of a preliminary injunction rests within the sound discretion of the district court. *Humana, Inc. v. Jacobson*, 804 F.2d 1390, 1392 (5th Cir. 1986). As set forth below, Xpress

Compounding has established all four elements justifying a preliminary injunction and preservation of the status quo during the pendency of this matter.

B. Xpress Compounding Has Established All Four Elements Justifying A Preliminary Injunction.

1. There Is A Substantial Likelihood That Xpress Compounding Will Prevail On The Merits Of Its Declaratory Relief Claim.

While Xpress Compounding must demonstrate that it is likely to prevail on the merits of its claim, “the likelihood of success need not be one of absolute certainty.” *Sebastian v. Tx. Dep’t of Corrections*, 541 F. Supp. 970, 975 (S.D. Tex. 1982). The movant is not required to prove its case. *Lakedreams v. Taylor*, 932 F.2d 1103, 1109 n.11 (5th Cir. 1991). Nor is it “necessary that the [movant’s] right to a final decision, after a trial, be absolutely certain [or] wholly without doubt.” *Sebastian*, 541 F. Supp. at 975. A reasonable probability of success is all that need be shown for preliminary injunctive relief. *Incubus Invs. L.L.C. v. City of Garland*, 2003 WL 23095680, at *3 (N.D. Tex. Dec. 17, 2003). For the reasons that follow, Xpress Compounding has presented a reasonable probability of success on its claims.

a. Prime Is Not Entitled To Terminate Xpress Compounding Without Cause Under Article 21.52B Of The Texas Insurance Code.

Xpress Compounding seeks a declaration that Prime is not entitled to terminate Xpress Compounding without cause under article 21.52B of the Texas Insurance Code. Doc 1-3 (Petition) at 6.

Texas Insurance Code Article 21.52B states as follows:

A health insurance policy or managed care plan that is delivered, issued for delivery, or renewed or for which a contract or other agreement is executed may not: . . .

(2) deny a pharmacy or pharmacist the right to participate as a contract provider under the policy or plan if the pharmacy or pharmacist agrees to provide pharmaceutical services that meet all terms and requirements and to include the

same administrative, financial, and professional conditions that apply to pharmacies and pharmacists who have been designated as providers under a policy or plan

TEX. INS. CODE art. 21.52B, § 2(a)(2). As interpreted by the Fifth Circuit, article 21.52B precludes a PBM, like Prime, from discriminating against pharmacies, who agree to abide by the same terms, requirements and conditions demanded of other network providers. *See Pharmacy Ass’n v. Prudential Ins. Co. of Am.*, 907 F. Supp. 1019, 1024 (W.D. Tex. 1995) (“The statute prohibits a pharmacy network operator, such as Prudential, from limiting provider participation in the network by any pharmacy or pharmacist who meets the standard terms and requirements established.”), *aff’d in part and rev’d in part*, 105 F.3d 1035, 1037 (5th Cir. 1997) (“The effect of the statute is that any pharmacist willing to abide by the terms of a Prudential network contract must be admitted to the network”) (emphasis added).

Xpress Compounding expressly asked Prime to identify what terms, conditions or requirements, if any, it had failed to comply with in its November 9, 2015 appeal letter. Ex. 3-L (App. 252-253). Notwithstanding this request, Prime has not and cannot identify any term, requirement or condition generally applicable to other pharmacies within Prime’s provider network with which Xpress Compounding has not agreed to comply. *See* Ex. 3-K (App. 251) (Oct. 22, 2015 letter); Ex. 3-M (App. 254) (Dec. 22, 2015 letter). Indeed, Xpress Compounding has expressly agreed to comply with all terms and conditions imposed on network participants in Prime’s network participation agreement with TriNet. Ex. 3-B (App. 042) (TriNet Third Party Network Addendum, at ¶ 1.1) (“Client [Xpress Compounding] agrees to comply with all Terms and Conditions set forth in all Pharmacy Benefit Manager (PBM) Network Agreements contracted by TriNet on Client’s behalf . . .”).

If, consistent with Prime’s failure to identify any substantive basis for excluding Xpress Compounding from its network, Prime has purported to terminate Xpress Compounding

“without cause,” such termination is directly contrary with the spirit and letter of article 21.52B. *See* TEX. INS. CODE art. 21.52B; *Prudential*, 907 F. Supp. at 1024 (“The stated ‘purpose’ of article 21.52B, when enacted, was ‘[t]o prohibit a contractual provision in an insurance policy which interferes with or limits the participant's ability to choose his own pharmaceutical provider.’”). Accordingly, Xpress Compounding is justified in seeking a declaration that Prime is not entitled to terminate Xpress Compounding without cause under article 21.52B of the Texas Insurance Code.¹

b. There Is No Valid Basis For Termination From Prime’s Network For Purposes Of Article 21.52B Of The Texas Insurance Code.

Despite Prime’s vague reference to so-called “poor audit performance,” there is no valid cause that would justify Xpress Compounding’s termination from Prime’s network for purposes of article 21.52B of the Texas Insurance Code. Over the past twelve months, Prime has conducted one site audit on January 28, 2015; issued a series of twenty-one desktop audits; and made one wholesaler inventory request. Ex. 3 (App. 014-015) (Paprskar Aff., ¶¶ 9, 12, 14). After corrections and an appeal, the January 28, 2015 site audit, which reviewed \$41,810.26 in claims submitted between September 2014 and November 30, 2014, resulted in a recoupment of only \$4,978.34 or 11.67% of all claims reviewed by revenue. *Id.* at ¶¶ 10-13 (App. 014); Ex. 3-G (App. 166-198) (Prime’s Sept. 3, 2015 appeal response). Prime’s twenty-one desktop audits did not result in any adverse finding or disciplinary action against Xpress Compounding. Ex. 3 (App. 014-015) (Paprskar Aff., ¶ 14); Ex. 3-H (App. 199-219) (desktop audit summary).

¹ *Prudential Ins. Co. of Am.*, 907 F. Supp. at 1024 (“The language of article 21.52B is clear. The statute prohibits a pharmacy network operator, such as Prudential, from limiting provider participation in the network by any pharmacy or pharmacist who meets the standard terms and requirements established.”); *cf. Kentucky Assoc. of Health Plans, Inc. v. Miller*, 538 U.S. 329, 332 (2003) (noting that Kentucky’s “Any Willing Provider” statutes “impair [the HMO’s] ability to limit the number of providers with access to their networks...”).

Nor did Prime's wholesaler invoice request. Ex. 3 (App. 015) (Paprskar Aff., ¶ 16); Ex. 3-J (App. 250) (Prime's wholesaler inventory request).

None of the audits performed prior to Prime's October 22, 2015 termination notice indicates an unwillingness on the part of Xpress Compounding to comply with the terms of any contract or other requirement imposed by Prime upon other pharmacies within its network. Ex. 3 (App. 014-015) (Paprskar Aff., ¶¶ 10-16); Ex. 3-G (App. 166-98) (Prime's appeal response); Ex. 3-H (App. 199-219) (audit summary); Ex. 4 (App. 256-257) (Alexander Aff., ¶ 6).

Even Prime's own Provider Manual does not justify termination based on minor audit exceptions. The manual provides that audits may result in payment recoveries, claim adjustment, corrective action plans and/or contract terminations. Ex. 3-I at 20 (App. 241). If every recoupment resulted in termination, as Prime's conduct suggests, there would be no need for claim adjustments or corrective action plans. Prime's correspondence makes no reference to a potential corrective action plan. *See* Ex. 3-K (App. 251) (Oct. 22, 2015 letter); Ex. 3-M (App. 254) (Dec. 22, 2015 letter).

The fact that Xpress Compounding's "audit performance" does not justify termination is confirmed by the experience of other pharmacies participating in other audits by PBMs. Pharmacies with comparable or even materially greater audit exceptions have not been terminated by other well-known PBMs, including CVS/Caremark and Humana. Ex. 4 (App. 256-57) (Alexander Aff., ¶¶ 4, 8, 9).² Prime's termination of Xpress Compounding on the basis of any audit performed preceding its December 22, 2015 termination letter is wholly unjustified. *Id.* at ¶ 7 (App. 257).

² Xpress Compounding does not currently have access to documentation showing the audit performance of other pharmacies in Prime's network, but anticipates seeking discovery establishing that other pharmacies in Prime's provider network have received poor audit reviews and more severe exceptions without being terminated.

Xpress Compounding has agreed to comply with the terms, requirements and standards imposed on other Prime pharmacies in the PBA Health Services Agreement. Ex. 3-B (App. 042) (TriNet Third Party Network Addendum, at ¶ 1.1) (“Client [Xpress Compounding] agrees to comply with all Terms and Conditions set forth in all Pharmacy Benefit Manager (PBM) Network Agreements contracted by TriNet on Client’s behalf . . .”). An agreement to comply is all that is required under article 21.52B. TEX. INS. CODE art. 21.52B, § 2(a)(2) (stating that a plan or policy may not “deny a pharmacy or pharmacist the right to participate as a contract provider under the policy or plan *if the pharmacy or pharmacist agrees to provide pharmaceutical services that meet all terms and requirements* and to include the same administrative, financial, and professional conditions that apply to pharmacies and pharmacists who have been designated as providers under a policy or plan” (emphasis added)). Prime has not and cannot claim that any audit exceptions demonstrate a material breach of the PBA or the PPA. Absent a breach of Xpress Compounding’s “agreement,” there is no basis to exclude Xpress Compounding under article 21.52B of the Texas Insurance Code.

c. Prime Is Required To Provide Xpress Compounding A Written Explanation For The Reasons For Its Termination Under Section 843.306(a) Of The Texas Insurance Code.

Under Texas Insurance Code Section 843.306(a), a health maintenance organization shall provide a “provider” with a written explanation of the reasons for termination. TEX. INS. CODE § 843.306(a). “Provider” includes, among others, “a pharmacy.” *Id.* § 843.002(24)(A)(ii). Although the statute expressly refers to HMOs, this provision applies equally to PBMs who administer contracts with pharmacy providers. TEX. ATT’Y GEN. OP. NO. KP-0036 (Aug. 14, 2015) (Exhibit 6) (App. 264); Ex. 1 (App. 004-005) (Hall Aff., ¶¶ 11-12) (Prime, like other PBMs, contracts with and administers claims on behalf of health insurance plans).

On November 9, 2015 Xpress Compounding responded to Prime's October 22, 2015 termination letter, asking Prime to identify what specific terms and conditions Prime believes Xpress Compounding violated, and with specific reference to Prime's audit findings over the past year, why. Ex. 3-L (App. 252-253) (Nov. 9, 2015 letter). Prime responded to Xpress Compounding's November 9, 2015 correspondence with a tersely worded denial letter, dated December 22, 2015. Ex. 3-M (App. 254). In that letter, Prime offers no explanation of its decision to terminate Xpress Compounding. Xpress Compounding is entitled under Section 843.306(a) of the Texas Insurance Code to the explanation that is lacking in any of Prime's correspondence regarding its imminent January 29, 2016 termination of the pharmacy from its provider network.

d. Xpress Compounding Is Entitled To Have Prime's Termination Decision Reviewed By An Advisory Review Panel Under Section 843.306(b) Of The Texas Insurance Code.

Texas Insurance Code Section 843.306(b) states that within 60 days of the provider's request and before the termination is effective, the provider is entitled to a review of the proposed termination by an "advisory review panel," which panel must be composed of "physicians and providers who are appointed to serve on the standing quality assurance committee or utilization review committee" and must include at least one pharmacy or pharmacist. *Id.* § 843.002(24)(A)(ii). This provision also applies equally to PMBs. TEX. ATT'Y GEN. OP. NO. KP-0036 (Aug. 14, 2015) (Exhibit 6) (App. 264).

In response to Prime's termination notice, Xpress Compounding demanded a review by an advisory review panel pursuant to Section 843.306(b). Ex. 3-L (App. 252-253) (Nov. 9, 2015 letter). Despite Xpress Compounding's request, Prime has not responded to Xpress Compounding's request for review of its decision by an advisory review panel. Ex. 3 (App. 016) (Paprskar Aff., ¶ 19); Ex. 3-M (App. 254) (Prime's Dec. 22, 2015 letter). Nor has Prime

otherwise demonstrated that its termination decision has been reviewed by a quality assurance committee or a utilization review committee under the statute. Accordingly, Xpress Compounding is entitled to review of Prime's termination decision by a statutory "advisory review panel" before the effective date of the termination. TEX. INS. CODE § 843.306(b). Xpress Compounding's request for injunctive relief enjoining Prime's imminent termination is justified on this basis alone.

2. Unless Enjoined, Prime's Wrongful Termination Will Result In Immediate, Irreparable Injury To Xpress Compounding And Its Patients.

"To show irreparable injury if threatened action is not enjoined, it is not necessary to demonstrate that harm is inevitable and irreparable. The plaintiff need show only a significant threat of injury from the impending action, that the injury is imminent, and that money damages would not fully repair the harm." *Humana*, 804 F.2d at 1394. Reputational harm and bodily harm are two examples of injuries for which monetary compensation is generally insufficient, justifying injunctive relief.³ Here, Prime's termination of Xpress Compounding will result in both loss of reputation and customer goodwill and increase the risk of patient harm.

a. Termination Will Cause A Loss Of Business, Reputation And Customer Goodwill For Existing And Future Patients.

In the compounding pharmacy business, a company's reputation for safe, quality compounded drugs among patients and physicians is vitally important to the success of the enterprise. Ex. 1 (App. 003-004) (Hall Aff., ¶ 8). In one recent, high-profile case, a compounding pharmacy, the New England Compounding Center ("NECC"), was linked to a fungal meningitis outbreak resulting in the deaths of more than fifty (50) patients and injuries to

³ See, e.g., *Austin Bd. of Realtors v. E-Realty, Inc.*, 2000 WL 34239114, at *5 (W.D. Tex. Mar. 30, 2000) (potential harm to a company's reputation constitutes irreparable harm); *Planned Parenthood of Cent. Tex. v. Sanchez*, 280 F. Supp. 2d 590, 610 (W.D. Tex. 2003) (the potential harm to patients resulting from the disruption of healthcare constitutes irreparable harm).

more than seven hundred (700) individuals.⁴ In the wake of the NECC debacle, compounding pharmacies have been subject to intense media and regulatory scrutiny.⁵ In the atmosphere of public skepticism created by these events, legitimate compounding pharmacies must rely on reputation and consumer goodwill to continue operations.

If Prime is not prevented from making its termination effective January 29, 2016, the termination will destroy Xpress Compounding's reputation and existing patient relationships. Ex. 1 (App. 005-006) (Hall Aff., ¶ 15) (“[U]nless enjoined, Prime’s termination of Xpress Compounding will result in the loss of Xpress Compounding’s customer relationships for all patients insured under health plans administered by Prime.”). Xpress Compounding will not only lose customer revenue—it will lose customer trust and loyalty as patients and physicians inevitably question the basis for Prime’s termination, however unjustified. Ex. 1 (App. 006) (Hall Aff., ¶ 17) (“If patients are given notice of Prime’s decision to terminate Xpress Compounding from its pharmacy provider network, Xpress Compounding’s reputation as a safe and reliable provider of quality pharmaceuticals will be significantly impaired. Patients and physicians will inevitably question the basis for Prime’s decision to terminate.”); Ex. 2 (App. 010) (Kretzschmar Aff., ¶ 11) (“[B]ased on my experience as a practitioner, termination of a pharmacy by a large pharmacy benefit manager like Prime raises questions about the cause for the termination and potential implications for the quality of its products. Without more information regarding the nature of the termination in this instance, Prime’s removal of Xpress

⁴ See, e.g., *In re Compounding Pharmacy, Inc. Prod. Liab. Litig.*, 496 B.R. 256, 260 (D. Mass. 2013); Kurt Eichenwald, *The Killer Pharmacy: Inside a Medical Mass Murder Case*, NEWSWEEK (Apr. 16, 2015), <http://www.newsweek.com/2015/04/24/inside-one-most-murderous-corporate-crimes-us-history-322665.html>.

⁵ See, e.g., Maggie Fox, *Don't Use Dallas Compounding Pharmacy Products, FDA Warns*, NBC NEWS (Aug. 16, 2013), <http://www.nbcnews.com/health/dont-use-dallas-compounding-pharmacy-products-fda-warns-6C10937607>; David Ott, *Balancing the DOD's Compounding Equation*, THE HILL (Apr. 1, 2015), <http://thehill.com/blogs/congress-blog/healthcare/237540-balancing-the-dods-compounding-equation>. (“While the vast majority of the industry is made up of pharmacists who simply want to get paid a fair price to make medications that help patients, a minority of bad actors have given compounding a bad name . . .”).

Compounding from its pharmacy provider network raises a red flag for physicians and patients, making both less likely to use its products going forward.”).

Xpress Compounding will also lose existing relationships with patients insured by non-Prime plans to the extent that referring physicians will be unlikely to distinguish between pharmacies among patients, preferring instead to refer all patients, regardless of plan or PBM, to a single compounding pharmacy. Ex. 2 (App. 009) (Kretzschmar Aff., ¶ 7) (“Because I am often unaware which pharmacy benefit managers, like Prime, service individual patient’s health plans, in the event of a termination, I would be unable to refer any existing patients to Xpress Compounding going forward, whether or not those patients were members of a health plan affiliated with Prime.”); *see also generally* Ex. 1 (App. 005) (Hall Aff., ¶ 14) (“Due to a practical inability to differentiate between patients insured under Optum-affiliated plans or other health plans, at least one referring physician has indicated that he will no longer be able to refer patients to Mission Pharmacy after Optum’s termination, regardless of the benefit plan or affiliated PBM insuring such patients.”).

Prime patients, who are unable to continue using Xpress Compounding after termination becomes effective on January 29, 2016, are likely to experience confusion, frustration and other negative emotions if they are compelled to undergo the burden, inconvenience and potential delays inherent in transitioning to another pharmacy. Ex. 5 (App. 261) (Howell Aff., ¶¶ 5-6) (When a PBM terminates a pharmacy, the customers “express[] great distress, anxiety and frustration” and “do not understand why they are no longer able to use [the terminated pharmacy] as their preferred pharmacy, particularly when they have valid health insurance coverage.”); Ex. 1 (App. 006) (Hall Aff., ¶ 17) (“Just as patients responded to Mission Pharmacy’s termination by Optum with emotions ranging from anger to grief, patients are likely

to express similar negative feelings when confronted with the necessity of transferring prescriptions to a different pharmacy.”); Ex. 2 (App. 010) (Kretzschmar Aff., ¶ 10) (“When I have overseen the transfer of prescriptions from one pharmacy to another in the past, patients have expressed confusion and frustration to my staff, sometimes directed at the outgoing pharmacy, if they are not able to obtain essential medications and have to undergo the administrative burden of transitioning to a new pharmacy.”). These negative experiences will destroy any accumulated goodwill the pharmacy now enjoys with its existing Prime customers. *Id.*

Moreover, as patients and physicians have these undesirable experiences, Xpress Compounding will inevitably lose an unknown number of future customers. Ex. 1 (App. 006) (Hall Aff., ¶ 16) (With Prime’s termination, Xpress Compounding “will also lose the opportunity to receive new referrals for future patients, whether from now current Prime patients or physicians, with whom Xpress Compounding might otherwise have done business and developed customer goodwill”); Ex. 2 (App. 009) (Kretzschmar Aff., ¶ 7) (“Because I am often unaware which pharmacy benefit managers, like Prime, service individual patient’s health plans, in the event of a termination, I would be unable to refer any existing patients to Xpress Compounding going forward, whether or not those patients were members of a health plan affiliated with Prime. Nor would I be able to refer future patients to Xpress Compounding for prescription medications.”); Ex. 5 (App. 262) (Howell Aff., ¶ 10) (Mission pharmacy “undoubtedly lost referrals and potential future customers because of the termination from Optum’s network.”); Ex. 4 (App. 258) (Alexander Aff., ¶ 13) (“[A] negative experience with Xpress Compounding by one customer may be communicated to others, resulting in a loss of relationships with both existing patients and future referrals.”). Termination would also harm Xpress Compounding’s

reputation and relationship with other PBMs, who inquire about network terminations in deciding whether to admit or renew (*i.e.*, credential or recredential) individual pharmacies as participants in other PBM networks. Ex. 3 (App. 016) (Paprskar Aff., ¶ 21).

The threat to Xpress Compounding's business and customer relationships is not merely theoretical. Other pharmacies who have been terminated from a network have reported a significant loss of business as existing customers transfer prescriptions to alternative suppliers. Ex. 1 (App. 005) (Hall Aff., ¶ 14); Ex. 5 (App. 262) (Howell Aff., ¶ 10). The imminent loss of reputation and customer goodwill if Prime's termination is permitted to take effect on January 29, 2016 justifies an injunction. *See e.g., Humana, Inc.*, 804 F.2d at 1392 (affirming hospital's injunction granted to avoid a significant loss of business, including a situation whereby "many physicians who direct their patients to Humana [would] treat their patients at other hospitals"). Indeed, other courts have granted injunctive relief to pharmacies facing termination from a network. *Dr. Mark Lynn & Assocs. PLLC v. Vision Serv. Plan Ins. Co.*, 2005 WL 2739160, at *2 (W.D. Ky. Oct. 21, 2005) (granting injunctive relief to optometrist which sued under Kentucky's Any Willing Provider Statute because, among other reasons, "[the optometrist] would probably lose a majority of its patients. It will be difficult, if not impossible, to calculate his monetary damages.").⁶

⁶ *See also Paduano v. Express Scripts Inc.*, Case No. 2:14-cv-05376-ADS-ARL (E.D.N.Y. Oct. 3, 2014) (Exhibit 7) (App. 269) (temporarily restraining PBMs from prohibiting a pharmacy from delivering prescriptions by USPS or other delivery service); *J.C. Penney Co. v. Giant Eagle, Inc.*, 813 F. Supp. 360, 370 (W.D. Pa. 1992) (granting pharmacy injunction against competitor on the basis of irreparable harm; customers who filled prescriptions at competitor was "not a complete picture of the damages" that pharmacy incurred and there was no way to measure what new customers might go elsewhere to have their prescriptions filled); *United Healthcare Ins. Co. v. AdvancePCS*, 2002 WL 432068, at *8 (D. Minn. Mar. 18, 2002) (AARP established threat of irreparable harm entitling it to preliminary injunction against pharmacy benefits manager by establishing loss of goodwill among its members who filled prescriptions); *PharMerica Corp. v. Mary Jo McElyea & Absolute Pharm., Inc.*, 2014 WL 1876271, at *4-5 (N.D. Ohio May 9, 2014) (pharmacy's injunction against former salesperson granted because her confidential knowledge could severely damage pharmacy's business).

b. Termination Will Result In Risk To Patient Health.

By definition, if Xpress Compounding is terminated from Prime’s provider network, patients receiving health benefits through a Prime-affiliated plan or policy will no longer be able to receive reimbursement or other payments for compounded pharmaceuticals from Xpress Compounding. Ex. 1 (App. 004-005) (Hall Aff., ¶ 12); Ex. 2 (App. 009) (Kretzschmar Aff., ¶ 7). For patients who use compounded medication, access to safe and effective compounded drugs is essential. Ex. 2 (App. 009) (Kretzschmar Aff., ¶ 7). Xpress Compounding enjoys a reputation as a reliable supplier of safe and effective prescriptions to patients. *Id.* ¶ 6 (App. 008-009). If Xpress Compounding were terminated from Prime’s network, Xpress Compounding’s patients would be required to find suitable pharmaceutical alternatives, which may take days or even weeks. *Id.* at ¶¶ 8-9 (App. 009-010) (“the process of identifying an appropriate replacement pharmacy can take days and in some cases weeks”); Ex. 5 (App. 261-262) (Howell Aff., ¶¶ 7, 9) (“Time is needed to identify a suitable alternative pharmacy. . . . Additional time is needed for doctors’ prescriptions to be transferred and filled once the new pharmacy has been identified. In some cases, patients will have to go for days without needed medications while this process runs its course.”); Ex. 1 (App. 005) (Hall Aff., ¶ 14); Ex. 4 (App. 258) (Alexander Aff., ¶ 14). If patients are not able to take appropriate prescription medications regularly, “some patients may experience increased pain, infection, scarring, extended recovery periods and other adverse side effects.” Ex. 2 (App. 009-010) (Kretzschmar Aff., ¶ 9); Ex. 4 (App. 258) (Alexander Aff., ¶ 14) (When transferring prescriptions, “if the customer is deprived of needed medication, patients may suffer negative consequences ranging from inconvenience to potentially serious health complications, including severe pain and infection”); Ex. 5 (App. 262) (Howell Aff., ¶ 9) (“When patients are unable to take their medications [due to transfer], serious health complications can arise.”).

Termination and the accompanying risks to patient health and loss of patient/customer relationships is imminent. Absent a preliminary injunction, Prime has notified Xpress Compounding that termination will take effect on January 29, 2016. Ex. 3-K (App. 251) (October 22, 2015 letter). The impending termination of Xpress Compounding from Prime's provider network, and the ensuing loss of business and risks to patient health qualify as imminent and irreparable injury warranting injunctive relief.⁷

3. Prime Will Sustain No Harm From The Preliminary Injunction Sought Herein, Much Less Any Harm That Outweighs The Immediate, Irreparable Harm To Xpress Compounding Absent An Injunction.

As outlined in detail above, Prime is not entitled to terminate Xpress Compounding under article 21.52B of the Texas Insurance Code. *See supra* Part (B)(1)(a)-(b). It is axiomatic that Prime can sustain no harm from its compliance with the Texas Insurance Code. The injunction requested herein, which enjoins Prime from taking action to exclude Xpress Compounding from its pharmacy provider network, will consequently result in no harm to Prime—much less any harm that outweighs the substantial, imminent and irreparable harm that will befall Xpress Compounding without an injunction.⁸ By comparison, the harm that will accrue to Xpress Compounding without an injunction is substantial, imminent and irreparable. *See supra*

⁷ *See, e.g., Planned Parenthood Ass'n of Hidalgo Cnty. v. Suehs*, 828 F. Supp. 2d 872 (W.D. Tex. 2012) (finding a substantial threat of irreparable injury from a significant loss of funding likely to result in layoffs and closure of clinics); *Planned Parenthood of Central Texas v. Sanchez*, 280 F. Supp. 2d 590, 610-611 (W.D. Tex. 2003) (preliminary injunction warranted in light of (1) the potential loss of funding that would result in closure of clinics; and (2) the potential patient risk for women unable to seek women's healthcare services); *see also Tex. Health Care Ass'n v. Bowen*, 710 F. Supp. 1109, 1114-1115 (W.D. Tex. 1989) (harm to nursing home businesses, including loss of long-term patient relationships, resulting from a lack of mental illness screening criteria constituted an immediate, irreparable injury); *Thomas v. Johnston*, 557 F. Supp. 879, 917 (W.D. Tex. 1983) (acknowledging irreparable harm where patients "face a substantial threat of receiving inadequate care in their ICF-MR facilities and of being discharged from those facilities"); *Austin Bd. of Realtors v. E-Realty, Inc.*, 2000 WL 34239114, at *5 (W.D. Tex. Mar. 30, 2000) (potential harm to a company's business from loss of MLS access constitutes irreparable harm).

⁸ *See, e.g., WB Music Corp. v. Big Daddy's Entm't, Inc.*, 2005 WL 2662553, at *3 (W.D. Tex. Oct. 18, 2005) (a music venue infringing on the plaintiff's copyrights would not be harmed by an injunction against infringing because it is not a burden to be required to follow the law).

Part (B)(2). Because Prime will sustain no harm whatsoever from the injunction requested herein, much less any harm that outweighs the injuries sustained by Xpress Compounding, injunctive relief is appropriate.⁹

4. Enjoining Prime From Terminating Xpress Compounding Will Not Undermine The Public Interest.

No public interest is served by allowing Prime to terminate Xpress Compounding from its provider network. Indeed, to the extent that (1) statutes passed by the Legislature reflect the public interest; and (2) the public has an interest in enforcing Texas law, the public has an interest in allowing patients broad access to the pharmacies of their choice.¹⁰ Because, for the reasons explained above, Prime's termination violates the Texas Insurance Code, an injunction enjoining termination of Xpress Compounding from Prime's pharmacy provider network during the pendency of this action serves the public interest.¹¹

Likewise, to the extent that an injunction preserves the status quo in numerous patient relationships with Xpress Compounding and ensures continuity of care and access to quality compounded medications,¹² the public interest is served, not disserved, by the relief sought in this application.¹³

⁹ See, e.g., *Dallas Cnty. v. Bureau of Justice Assistance*, 988 F. Supp. 1030, 1031 (W.D. Tex. 1996) (finding that the Bureau of Justice Assistance, which had been improperly administering the Local Law Enforcement Block Grant Program, could not be harmed by an injunction that enjoined it from improperly carrying out an act of Congress).

¹⁰ TEX. INS. CODE art. 21.52B, § 2(a)(2) (prohibiting health insurance policies and managed care plans from excluding pharmacies that agree "to provide pharmaceutical services that meet all terms and requirements and to include the same administrative, financial, and professional conditions that apply to pharmacies and pharmacists who have been designated as providers under the policy or plan").

¹¹ See, e.g., *Daniels Health Sciences v. Vascular Health*, 710 F.3d 579, 585 (5th Cir. 2013) (finding no abuse of discretion by trial court in granting injunction on the basis that, in part, "the public is served when the law is followed."); *Tex. Democratic Party v. Benkiser*, 459 F.3d 582, 595 (5th Cir. 2006) ("It is beyond dispute that the injunction serves the public interest in that it enforces the correct and constitutional application of Texas's duly-enacted election laws."); cf. *Union Planters Bank, N.A. v. Gavel*, 2003 WL 1193671, at * 8 (E.D. La. Mar. 12, 2003) ("[T]he injunction in no way would disserve the public interest as the injunction would merely uphold and enforce a federal statute.").

¹² Ex. 1 (App. 005-006) (Hall Aff., ¶ 15) ("Prime's termination of Xpress Compounding will result in the loss of Xpress Compounding's customer relationships for all patients insured under health plans administered by Prime. Xpress Compounding will also lose existing relationships with patients insured by non-Prime plans to the extent that

IV. PRAYER

WHEREFORE, Plaintiff Hall's IV and Institutional Pharmacy, Inc. d/b/a Xpress Compounding respectfully requests that this Court (1) grant the foregoing Motion; (2) enter a preliminary injunction restraining and enjoining Prime, and its agents, servants, employees, representatives and all persons or entities acting in concert with them from:

- (a) Taking any action whatsoever to terminate or remove Xpress Compounding from any Prime pharmacy provider network;
- (b) Notifying Prime's members or prospective members of any termination or removal of Xpress Compounding from any Prime pharmacy provider network;
- (c) Without altering the payment requirements or claims process provided for under the Agreement between the parties or under any statute or rule, refusing to process or pay claims for payment submitted by Xpress Compounding based on the assertion that Xpress Compounding is no longer a member of the Prime pharmacy provider network;

and (3) grant Xpress Compounding any and all additional relief to which it may be justly entitled.

referring physicians will be unlikely to distinguish between pharmacies among patients"); Ex. 2 (App. 009) (Kretzschmar Aff., ¶ 7) ("If termination of Xpress Compounding is permitted to go forward . . . I would be unable to refer any existing patients to Xpress Compounding going forward, whether or not those patients were members of a health plan affiliated with Prime.").

¹³ *Teladoc, Inc. v. Tex. Med. Bd.*, 2015 WL 4103658, at *12 (W.D. Tex. May 29, 2015) (finding that the fourth factor of the injunction analysis weighed in favor of granting an injunction because the disruption of Teladoc's services would result in patients facing higher prices for medical care and reduced access to medical care).

Respectfully submitted,

/s/ Micah E. Skidmore

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D/B/A XPRESS COMPOUNDING

CERTIFICATE OF CONFERENCE

I hereby certify that on the 12th day of January, 2016, I conferred with counsel for Prime Therapeutics, LLC regarding the relief sought in the foregoing motion. Counsel for Prime Therapeutics is opposed to the relief sought in this motion.

I also conferred with counsel for Defendant regarding his availability for a hearing on this motion on January 19th or January 20th. Plaintiff is available to proceed with this motion on those dates. Defendant did not agree to a hearing on the motion on those dates. The parties will continue to confer and provide the Court with additional dates on which this motion could be heard in a supplemental Certificate of Conference.

/s/ Micah E. Skidmore

Micah E. Skidmore

CERTIFICATE OF SERVICE

I hereby certify that on the 15th day of January, 2016, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system which will send notification of such filing to the following:

Blake A. Bailey
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/s/ Natalie DuBose

Natalie DuBose

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